Notice of Allowability	Application No.	Applicant(s)	
	10/019,318	FUKAE, MASAFUMI	
	Examiner	Art Unit	
	Karl J. Puttlitz	1621	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.			
1. X This communication is responsive to <u>Amendments of 4/19/2004</u> .			
2. 🗵 The allowed claim(s) is/are <u>1-8,10-34 and 36-53</u> .			
3. The drawings filed on are accepted by the Examiner.			
<ul> <li>4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some* c) None of the:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* Certified copies not received: JP 2000-352892 JP 2000-330339 JP 2000-141717</li> <li>Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.</li> </ul>			
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.			
<ul> <li>6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. <ul> <li>(a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached</li> <li>1) hereto or 2) to Paper No./Mail Date</li> <li>(b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date</li> <li>Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).</li> </ul> </li> <li>7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.</li> </ul>			
Attachment(s)  1. Notice of References Cited (PTO-892)  2. Notice of Draftperson's Patent Drawing Review (PTO-948)  3. Information Disclosure Statements (PTO-1449 or PTO/SB/O Paper No./Mail Date  4. Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. ☐ Interview Paper No 98), 7. ☐ Examiner	Informal Patent Application (PTO-15 Summary (PTO-413), o./Mail Date s Amendment/Comment s Statement of Reasons for Allowar 	

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## **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Edward Kenehan on April 19, 2004.

Cancel claims 9 and 35;

Claim 1, line 1, replace "A crystallization method of" with "A method for crystallizing";

Claim 1, line 3, replace "which comprises" with "comprising";

Claim 28, line 1, replace "A crystallization method of" with "A method for crystallizing";

Claim 28, line 3, replace "which comprises" with "comprising";

Claim 1, line, 8, after "anhydride" insert ",wherein the good solvent is a halogenated hydrocarbon, an ether, a nitrile, an ester, a ketone or a mixed solvent thereof";

Claim 10, line 1, replace "9" with "1";

Claim 11, line 1, replace "9" with "1";

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Claim 28, line, 8, after "anhydride" insert ",wherein the good solvent is a halogenated hydrocarbon, an ether, a nitrile, an ester, a ketone or a mixed solvent thereof";

Claim 36, line 1, replace "35" with "28";

Claim 38, line 1, replace "35" with "28".

The following is an examiner's statement of reasons for allowance:

The claimed invention is drawn to a crystallization method of N-(1(s)-ethoxycarbonyl-3-phenylpropyl)-L-alanine N-carboxylic anhydride which comprises mixing a solution of the compound in a solvent, which is a halogenated hydrocarbon, an ether, a nitrile, an ester, a ketone or a mixed solvent thereof with an aliphatic hydrocarbon solvent to crystallize said N-carboxylic anhydride, the solution of said N-carboxylic anhydride in the good solvent being added to the aliphatic hydrocarbon solvent to thereby effect crystallization while inhibiting an oil formation and scaling of said N-carboxylic anhydride.

Notwithstanding the fact that purification by crystallization is a routine procedure, a search of the prior art has failed to teach or suggest crystallization of N-(1(s)-ethoxycarbonyl-3-phenylpropyl)-L-alanine N-carboxylic anhydride in a solvent which is a halogenated hydrocarbon, an ether, a nitrile, an ester, a ketone or a mixed solvent thereof. Moreover, the prior art is silent that the claimed method inhibits an oil formation and scaling of said N-carboxylic anhydride.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday-Friday (alternate).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Karl J. Puttlitz
Assistant Examiner

Johann R. Richter, Ph.D., Esq. Supervisory Patent Examiner

Biotechnology and Organic Chemistry

Art Unit 1621 (571) 272-0646